QV SKIN LOTION
PL 18278/0006

UKPAR

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LAY SUMMARY

The MHRA today granted Ego Pharmaceuticals (UK) Limited a Marketing Authorisation (licence) for the medicinal product QV Skin Lotion (PL 18278/0006). This is a general sales licence (GSL) for use as an emollient for the symptomatic relief of dermatological conditions associated with dry skin, including ichthyosis, pruritis hiemalis, atopic dermatitis, eczema, psoriasis and exposure to sun, wind and cold weather.

QV Skin Lotion contains the active ingredient white soft paraffin and acts as an emollient for dry skin.

No new or unexpected safety concerns arose from these applications and it was therefore judged that the benefits of using QV Skin Lotion outweighed the risks, hence a Marketing Authorisation has been granted.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy the UK granted a marketing authorisation for the medicinal product QV Skin Lotion to Ego Pharmaceuticals (UK) Limited (PL 18278/0006) on 24th August 2006. The product has a general sales licence (GSL).

The application was submitted as an abridged application according to Article 10a of Directive 2001/83/EC, a bibliographic application.

The product contains the active ingredient white soft paraffin and is indicated for use as a symptomatic relief of dermatological conditions associated with dry skin, including ichthyosis, pruritis hiemalis, atopic dermatitis, eczema, psoriasis and exposure to sun, wind and cold weather.

PHARMACEUTICAL ASSESSMENT

DRUG SUBSTANCE

RINN	White Soft Paraffin, White Petroleum Jelly
Chemical name:	Petrolatum
Other name:	Bentley Wax 1832 (BW 1832)
Physical form:	Semi-solid
Molecular formula:	C 20 to C50 - mixture of straight and branched chain paraffin's.
Molecular weight:	500 (mass average molecular weight)
Stereoisomerm/chirality:	No
Polymorphism:	No

Synthesis of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

An appropriate specification is provided for the active substance white soft paraffin that complies with the current Ph Eur/BP monographs.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

All potential known impurities have been identified and characterised.

Batch analysis data are provided that comply with the proposed specification.

The container used for storage of the active substance is satisfactory.

Appropriate stability data have been generated and no indication of instability seen. The data support a retest period of 24 months.

DRUG PRODUCT

Other ingredients

Other ingredients consisted of pharmaceutical excipients C12-C15 alkyl benzoate, carbomer 934P, cetomacrogol 1000, cetostearyl alcohol, dimethicone 350, glycerol, glyceryl monostearate, steareth-2, triethanolamine, dichlorobenzyl alcohol, water purified, methyl hydroxybenzoate and propyl hydroxybenzoate. With the exception of C12-C15 alkyl benzoate, steareth-2 and dichlorobenzyl alcohol (which all comply with suitable in-house specifications), all excipients used comply with their respective Ph Eur or BP monograph. The applicant has stated that the ingredients have been chosen for their emollient or humectant properties.

Satisfactory certificates of analysis have been provided for all excipients.

With the exception of glycerol, none of the excipients used contain material of animal or human origin. A comprehensive risk assessment has been performed on glycerol

such that a certificate of suitability is not required and it can be assumed that the glycerol produced is not susceptible to TSE.

Manufacture
A satisfactory description and flow-chart of the manufacturing method has been provided.

In-process controls are satisfactory based on process validation data and controls on the finished product. Process validation has been carried out on full-scale batches of the product. The batch analysis data show that product that complies with the target specification can be manufactured on a routine basis.

Bioavailability
There are no bioavailability studies as the product is intended for topical application. As the active ingredient does not require systemic absorption for its effect. Consequently, this omission is acceptable.

Finished product specification
The finished product specification is satisfactory. Test methods have been described and have been adequately validated as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis have been provided for any working standards used.

Container Closure System
Specifications and Certificates of Analysis for the primary packaging material have been provided. These are satisfactory. All primary packaging is controlled to Ph Eur standards. The finished product is packed in a high density polyethylene bottle with a polypropylene closure and is presented in pack sizes of 15ml, 250ml, 500ml and 1000ml.

Stability
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 5 years has been set, which is satisfactory.

Conclusion
It is recommended that a Marketing Authorisation is granted for this application.

PRECLINICAL ASSESSMENT

As this is a bibliographic application containing an active substance (white soft paraffin) that has been used in products for over 20 years, it was not considered necessary to perform a preclinical assessment.

CLINICAL ASSESSMENT

1. INDICATIONS

QV Skin Lotion is for use as a symptomatic relief of dermatological conditions associated with dry skin, including ichthyosis, pruritis hiemalis, atopic dermatitis, eczema, psoriasis and exposure to sun, wind and cold weather.

Suitable for use in infants and the elderly.

The indications are satisfactory for a product of this type.

2. DOSE & DOSE SCHEDULE

For cutaneous use. The lotion should be applied as required to the affected skin area as often as required, especially after showering, bathing, shaving, exposure to harsh climatic conditions and at night

3. TOXICOLOGY

No new data submitted

4. CLINICAL PHARMACOLOGY

No new data submitted

5. EFFICACY

No data submitted

6. SAFETY

No data submitted

7. EXPERT REPORTS

A comprehensive clinical expert report written by an appropriately qualified physician has been submitted.

8. PATIENT INFORMATION LEAFLET (PIL)

Satisfactory.

9. LABELLING

Satisfactory.

10. APPLICATION FORM (MAA)

Satisfactory.

11. SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

Satisfactory.

12. MEDICAL CONCLUSION

It is recommended that a Marketing Authorisation be granted.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of QV Skin Lotion are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL

No new preclinical studies were conducted. The preclinical data submitted have not revealed any evidence of potential risks to human health.

EFFICACY

No new or unexpected safety concerns arise from this application.

The SPC and PIL are satisfactory and consistent with that for the reference products.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Extensive clinical experience with the active substance is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.

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STEPS TAKEN FOR ASSESMENT

1.	The MHRA received the marketing authorisation application on 21st December 2000
2.	Following standard checks and communication with the applicant the MHRA considered the application valid on 10th January 2001
3.	Additional clinical and pharmaceutical information was requested on 24th May 2001
4.	Additional pharmaceutical and clinical information was provided on 11th October 2002
5.	Further pharmaceutical information was requested from the applicant on 20th February 2003, 11th June 2003 and 28th May 2004
6.	Further pharmaceutical information was provided on 20th May 2003, 20th August 2003 and 18th January 2006
7.	The application was determined on 24th August 2006

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STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

QV Skin Lotion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

White Soft Paraffin 5 % w/w

For excipients see 6.1

3. PHARMACEUTICAL FORM

Cutaneous Solution

White to off-white solution

4 CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the symptomatic relief of dermatological conditions associated with dry skin including:

- Ichthyosis
- Pruritis hiemalis
- Atopic dermatitis
- Eczema
- Psoriasis
- Exposure to sun, wind and cold weather.

Suitable for use in infants and the elderly

4.2. Posology and Method of Administration

Administration:

For cutaneous (topical) administration only.

Dosage:

The lotion should be applied as required to the affected skin area as often as required, especially after showering, bathing, shaving, exposure to harsh climatic conditions and at night

4.3. Contra-indications

Hypersensitivity to any of the ingredients of the preparation.

4.4. Special Warnings and Precautions for Use

The lotion is for external use only.

QV Skin Lotion contains Cetostearyl alcohol which may cause local skin reactions e.g. contact dermatitis.

QV Skin Lotion contains Methyl parahydroxybenzoate and Propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

Avoid contact with the eyes. Upon accidental contact, flush with clear water.

To avoid further irritation of sensitive skin do not use soap on the affected area.

If the condition does not improve or is aggravated discontinue use and consult the doctor.

4.5. Interactions with other Medicaments and other forms of Interaction

No known interactions.

4.6. Pregnancy and Lactation

There is no evidence of the safety of QV Skin Lotion in human pregnancy and lactation, but the constituents of the preparation have been in wide use for many years without apparent ill consequences.

4.7. Effects on Ability to Drive and Use Machines

Not applicable.

4.8. Undesirable Effects

No known undesirable effects.

4.9. Overdose

No case of overdose has been reported

5 PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Pharmacotherapeutic group: Other emollients and protectives, ATC Code: D02A C

The formulation contains white soft paraffin BP (5% w/w) which is primarily responsible for the emollient characteristics of the product i.e. it forms a layer over the skin that retards the loss of water through the stratum corneum. It is the moisture that is retained as a result of this occlusive effect of white soft paraffin that keeps the skin soft and pliable.

5.2. Pharmacokinetic Properties

For local application only.

5.3. Preclinical Safety Data

The actives are a well-established emollient remedy. They have been safely and effectively used in topical applications for a number of decades.

6 PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

C12-15 Alkyl benzoate

Carbomer

Macrogol cetostearyl ether

Cetostearyl alcohol

Dimeticone

Glycerol

Glyceryl monostearate

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate (E216)

Purified water

Steareth - 2

Trolamine

Dichlorobenzyl Alcohol

6.2. Incompatibilities

None Known

6.3. Shelf Life

Five years.

6.4. Special Precautions for Storage

No special precautions for storage

6.5. Nature and Contents of Container

250mL, 500mL and 1 litre white pre-printed HDPE bottles fitted with white polypropylene caps.

15ml white pre-printed HDPE bottles fitted with white polypropylene cap as sample pack

6.6. Instruction for Use/Handling

No special requirements

7. Marketing Authorisation Holder

Ego Pharmaceuticals (UK) Limited

15 Windsor Park, 50 Windsor Avenue,
Merton,
London SW19 2TJ

United Kingdom.

8. Marketing Authorisation Number

PL 18278/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/08/2006

10 DATE OF REVISION OF THE TEXT

24/08/2006

QV Skin Lotion		
Ego Version 11	Prepared: June 2006	Country: UK

Patient Information Leaflet
QV Skin Lotion
(White Soft Paraffin)

Please read this information carefully before you start to use QV Skin Lotion as it has been prepared to tell you about the product and to help you use it correctly. However, it does not contain all the available information about QV Skin Lotion, so if you have any further questions, please ask your doctor or pharmacist.

Please keep this leaflet in a safe place as you may wish to look at it again while you are using QV Skin Lotion.

The name of your product is QV Skin Lotion

QV Skin Lotion is a white to off white lotion. The active ingredient is White Soft Paraffin 5%.

The other ingredients are C12-15 alkyl benzoate, carbomer, macrogol cetostearyl ether, cetostearyl alcohol, dichlorobenzyl alcohol, dimeticone, glycerol, glyceryl monostearate, steareth-2, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), trolamine and purified water.

pH 6: The pH of your skin is pH 6. QV Skin Lotion is manufactured at this pH to be mild and gentle on the skin.

QV Skin Lotion is free from lanolin, perfume and colour to avoid further irritation to people who may be sensitive to these ingredients.

QV Skin Lotion is available in 250 mL, 500 mL and 1 litre bottles.

About QV Skin Lotion

The active ingredient in QV Skin Lotion belongs to a group of medicines known as moisturisers, which have been found to be effective in reducing the dryness of the skin and protecting the skin.

White soft paraffin forms a protective layer over the skin surface, which slows down the loss of water. The retention of this water keeps the skin soft and pliable.

Marketing Authorisation Holder
Ego Pharmaceuticals (UK) Limited
15 Windsor Park,
50 Windsor Avenue,
Merton, London, SW19 2TJ
United Kingdom

Manufacturer
Crawford Healthcare Limited
Cheshire House
164 Main Road, Goostrey
Cheshire, CW4 8JP
United Kingdom

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What is QV Skin Lotion for

QV Skin Lotion has been specially formulated to provide a non-greasy, non-sticky, soothing moisturiser for use on dry, cracked or damaged skin. QV Skin Lotion provides relief to itchy, dry skin by soothing and softening the skin. QV Skin Lotion also helps prevent dry skin.

QV Skin Lotion is recommended to help relieve dry, skin in a wide range of skin conditions such as psoriasis (inflammation of the skin), ichthyosis (scaly skin), pruritis hiemalis (scaly winter itch), atopic dermatitis (changes in the skin surface), eczema, and exposure to sun, wind and cold weather.

QV Skin Lotion is suitable for use with other products in the treatment of dry skin conditions in infants and the elderly.

QV Skin Lotion		
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Before you use QV Skin Lotion

Before you use QV Skin Lotion, please note;

- Check the list of ingredients stated above. If you are sensitive (have allergies), to any of them do not use this product.
- ***Important information about some of the ingredients of QV Skin Lotion:*** QV Skin Lotion contains cetostearyl alcohol which may cause local skin reactions e.g. contact dermatitis. QV Skin Lotion contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic skin reactions, possibly delayed
- ***Pregnancy, breastfeeding:*** If you are breast feeding or pregnant or are thinking of starting a family, please talk to your doctor before using QV Skin Lotion.
- ***Driving and using machinery:*** QV Skin Lotion will not affect your ability to drive or operate machinery
- ***Taking other medicines:*** Please inform your doctor or pharmacist if you are using or taking any other medicines or creams, even those not prescribed

If you are not sure about using QV Skin Lotion, please talk to your doctor or pharmacist.

Advice when using QV Skin Lotion

- Keep the QV Skin Lotion away from the eyes. If it accidentally gets into the eyes, flush them with clear water.
- As soap can irritate skin, you may benefit from using a soap substitute rather than ordinary soap on dry areas of skin.

If your skin problem becomes worse or you have a reaction, stop using QV Skin Lotion and tell your doctor or pharmacist immediately.

How to use QV Skin Lotion

For use on the body, face and hands.

For External Use Only

QV Skin Lotion should be applied as required, especially after showering, bathing, shaving or exposure to harsh weather conditions and at night.

- First wash and dry the affected areas.
- Apply QV Skin Lotion with clean hands to the affected area of the skin.
- Apply to the skin, rubbing it well in, until it is not visible on the skin surface.
- Replace the cap after use.

QV Skin Lotion can soften and protect the skin before or after bathing or showering.

After using QV Skin Lotion

QV Skin Lotion is very effective and most people do not usually have any problems. If you experience any irritation or any other unwanted effects, stop using QV Skin Lotion and tell your doctor.

QV Skin Lotion may not work immediately, however if your condition does not improve you should tell your doctor.

If you follow the instructions for use, it should not be possible to use too much. If QV Skin Lotion is accidentally swallowed, you should contact your doctor immediately.

If you are not sure about using QV Skin Lotion, please talk to your doctor or pharmacist.

Storing QV Skin Lotion

- Always replace the cap after using QV Skin Lotion to avoid contamination of the lotion and to keep it as clean as possible during use.
- If the "expiry date" on the label has passed, stop using QV Skin Lotion and dispose of it safely, such as by giving it to your pharmacist.

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- You should never give your QV Skin Lotion to anyone else to use, even if they appear to have the same symptoms as you.
- Always keep QV Skin Lotion in a safe place out of the reach and sight of children.

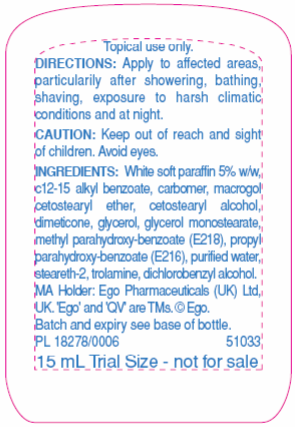
Further Information

Further information is available from your doctor and pharmacist

Date of preparation: June 2006, version 11

15 Millilitre Pack

The batch number and expiry date are printed on the base of the carton, as stated on the label.



The batch number and expiry date are printed on the base of the bottle, as stated on the label.

250 Millilitre Pack

The batch number and expiry date are printed on the base of the carton, as stated on the label.

The batch number and expiry date are printed on the base of the bottle, as stated on the label.

500 Millilitre Pack

The batch number and expiry date are printed on the base of the carton, as stated on the label.

The batch number and expiry date are printed on the base of the bottle, as stated on the label.

1 Litre Pack

The batch number and expiry date are printed on the base of the carton, as stated on the label.

The batch number and expiry date are printed on the base of the bottle, as stated on the label.